DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date DEC 16 1996

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Bausch & Lomb, Inc.'s BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by Eleanor M. Felton, CDRH, HFZ-460, August 7, 1996, 594-1744

A

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

BAUSCH & LOMB, INC.; PREMARKET APPROVAL OF BAUSCH & LOMB® SOFLENS66™ (ALPHAFILCON A) VISIBILITY TINTED CONTACT LENS FOR EXTENDED WEAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bausch & Lomb, Inc., Rochester, NY, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 16, 1996, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

B

FOR FURTHER INFORMATION CONTACT:

James F. Saviola, O.D.,
Center for Devices and Radiological Health (HFZ-460),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-1744.

SUPPLEMENTARY INFORMATION: On June 28, 1996, Bausch & Lomb, Inc., Rochester, NY 14692-0450, submitted to CDRH an application for premarket approval of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear. The device is a soft (hydrophilic) contact lens and is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates

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information previously reviewed by this panel.

On December 16, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.The labeling of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under

§10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dennis Hahn
Manager, Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 N. Goodman Street
P.O. Box 450
Rochester, NY 14692-0450

DEC 16 1996

Re: P960022
BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear
Filed: June 28, 1996
Amended: July 12, October 30, and November 6, 1996

Dear Mr. Hahn:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear. This device is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon

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which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mrs. Eleanor M. Felton or James F. Saviola, O.D. at (301) 594-1744.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Enclosure

Issued: 5-2-95

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

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A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant**(s)** involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

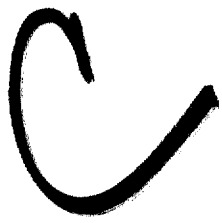
The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857



Summary of Safety and Effectiveness

I. General Information

A. Premarket Approval Application (PMA) Number: P960022
Date Filed: June 28, 1996
Date Approved: DEC 16 1996

B. Device Generic Name: alphafilcon A soft (hydrophilic) contact lens

C. Device Trade Name: BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear

D. Applicant's Name and Address:
Bausch & Lomb, Inc.
1400 N. Goodman Street
P.O. Box 450
Rochester, NY 14692-0450

E. Good Manufacturing Practice (GMP) Inspection:
Dates of Inspection: February 23, 1995; and January 22, 1996
Conclusion: The manufacturing sites were found to be in compliance with device GMP requirements.

II. Indications

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Extended Wear is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

III. Summary

The SofLens66™ (alphafilcon A) is identical to the currently marketed B&L SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens for Daily Wear cleared under K941370. The applicant performed non-clinical and additional clinical testing on the device for extended wear based on the FDA Guidance Document for Class III Soft (Hydrophilic) Contact Lenses dated April 1989, with modification to include a controlled clinical study. The non-clinical testing supports the safety and effectiveness of the device from microbiology, toxicology, chemistry and

manufacturing perspectives. Data were evaluated from a controlled, randomized, double-masked, multicenter parallel group clinical study consisting of 430 completed eyes in the Test Group using the subject device and 186 completed eyes in a Control Group wearing the B&L 70 Lens. The subjects in both groups were followed for 12 months and clinically evaluated. The completed Test Group included 66 males and 149 females and the completed Control Group included 38 males and 55 females which is representative of the contact lens wearing population in the United States. Although the potential exists for minor differences in physiological response by gender for the target population, the minimal number of clinically significant findings does not indicate gender difference to be of clinical importance for this device.

IV. Safety and Effectiveness Data

A. Non-clinical Data

The applicant conducted a battery of in-vivo and in-vitro acute toxicology studies that support the safety and biocompatibility of the lens material with solutions for use with soft (hydrophilic) contact lenses. Additionally, chemistry and manufacturing information was submitted demonstrating that the lens material is suitable for use by humans. The adequacy of the manufacturing process, including sterilization and shelf-life expiration dating, was established through a review of the manufacturing and microbiology data submitted in the PMA as well as through an on-site GMP inspection.

B. Clinical Data (Test Group)

Accountability (604 eyes enrolled): 430 completed and 174 discontinued*
(* 9 with positive slit lamp findings)

Visual Acuity:	Initial Visit with Lens	Final Visit with Lens
20/30 or better	428	385
20/40 or worse	2	4
Not Reported	0	41

Wear Time:	Initial Adapted (4-days)	Final (12 months)
Extended	3 days	7 days

Adverse Reactions: 5 reported. 2 reports of bacterial conjunctivitis; 2 reports of chemical conjunctivitis; and 1 report of infiltrates and diffuse punctate keratitis. None were lens related and all cleared.

Slit Lamp Findings:	Initial Visit (38/430 eyes)=8.8%	Final Visit (67/430 eyes)=15.6%
Bulbar injection	12	14
Staining	18	19
Microcysts	0	4
Edema	0	3
Limbal Injection	8	13
TCA	0	14

Symptoms, Problems, Complaints: 2069 positive reports, 37% (n= 5586)

Categories reported=10	
Vision Related (e.g. blurred vision)	(513/2069)=24.8%
Comfort (e.g. dryness, itching)	(1408/2069)=68.1%
All Other	(148/2069)= 7.2%

Lens Replacements: 781 replaced/430 dispensed=1.8 lenses per eye*
(*Multiple replacements and multiple reasons cited)

Categories reported=10	
Vision Related (e.g. fit, power change)	(138/781)=17.7%
Lens Related (e.g. damaged)	(272/781)=34.8%
Other (e.g. deposits, lost)	(371/781)=47.5%

C. Clinical Data (Control Group)

Accountability (238 eyes enrolled): 186 completed and 52 discontinued*
(*3 with positive slit lamp findings and 1 with repeated ocular infections)

Visual Acuity:	Initial Visit with Lens	Final Visit with Lens
20/30 or better	186	174
20/40 or worse	0	0
Not Reported	0	12

Wear Time:	Initial Adapted (4-days)	Final (12 months)
Extended	3 days	7 days

Adverse Reactions: None reported for all eyes enrolled

Slit Lamp Findings:	Initial Visit (20/186 eyes)=10.8%	Final Visit (26/186 eyes)=14.0%
Bulbar injection	6	5
Staining	8	13
Microcysts	0	2
Edema	2	2
Limbal injection	2	0
TCA (Total)	0	2
> grade 2	0	1
Other (OASA)	0	2

Symptoms, Problems, Complaints: 959 positive reports, 39% (n= 2462)

Categories reported=10	
Vision Related (e.g. blurred vision)	(200/959)=20.9%
Comfort (e.g. dryness, itching)	(698/959)=72.8%
All Other	(61/959)=6.4%

Lens Replacements: 463 replaced/186 dispensed= 2.5 lenses per eye*
(*Multiple replacements and multiple reasons cited)

Categories reported=10	
Vision Related (e.g. fit, power change)	(52/463)=11.2%
Lens Related (e.g.defect)	(147/463)=31.7%
Other (e.g. discomfort, lost)	(264/463)=57.0%

Based on the detailed analysis of the data presented in the PMA, it was determined that the clinical findings for the Control Group and Test Group, i.e., adverse reactions, positive slit lamp findings, patient symptoms, problems and complaints, visual acuity, lens replacements, discontinued patients, and lens wearing time were within expected limits for soft (hydrophilic) contact lens wearers. Any differences in these groups do not raise concerns about the safety and effectiveness of the device when accompanied by appropriate labeling.

V. Conclusion

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device for the prescribed indications for use. This PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA submission duplicated information previously reviewed by that panel. CDRH approved this PMA in a letter to the applicant dated DEC 16 1996 and signed by the Director, Office of Device Evaluation.

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Labeling

HOW SUPPLIED

Each sterile lens is supplied in a plastic package containing borate buffered saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, diameter and expiration date.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
Rochester, New York 14692

Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720

BAUSCH
& LOMB

BAUSCH
& LOMB

SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses

IMPORTANT: This package insert is effective as of December 1996 and supersedes all prior inserts for the products described below. Please read carefully and keep this information for future use.

This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

CAUTION: Federal (U.S.A.) Law Prohibits Dispensing Without Prescription.

Bausch & Lomb Incorporated
Rochester, NY 14692

DPI0001 12/96 Printed in U.S.A.

Multifold label pages 1-8
Fitting Guide pages 9-15
Patient Label pages 16-

the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes.) Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lens.

Note: Use of heat disinfection unit should be resumed as soon as possible.

- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Chemical (Not Heat) Disinfection:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- **After cleaning and rinsing,** to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses **must be neutralized** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- **Do not heat the disinfection solution and lenses.**
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE

Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals.

CARE FOR A DRIED OUT (DEHYDRATED) OR DRY LENS

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply saline or rinsing solution before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, the len should not be used until examined by the eye care practitioner.

CARE FOR A STICKING (NONMOVING) LENS

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in th eye. The patient should be instructed to not use plain wa or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking a several applications of the solution.

PRACTITIONER FITTING SETS

All lenses that have been opened must be discarded aft use.

EMERGENCIES

The patient should be informed that if chemicals of any (household products, gardening solutions, laboratory ch icals, etc.) are splashed into the eyes, the patient shoul FLUSH EYES IMMEDIATELY WITH TAP WATER AND TH REMOVE LENSES PROMPTLY. CONTACT THE EYE CAR PRACTITIONER OR VISIT A HOSPITAL EMERGENCY RO WITHOUT DELAY.

	BAUSCH & LOMB® SENSITIVE EYES® Plus
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Thermal Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® SENSITIVE EYES® Enzymatic Contact Lens Cleaner

Chemical Lens Care System

Action	Care Product
Cleaning	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Disinfecting & Storing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
Rinsing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Saline Solution
	BAUSCH & LOMB® ReNu® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray
	BAUSCH & LOMB® SENSITIVE EYES® Plus
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner
	Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® ReNu® 1 Step Enzymatic Contact Lens Cleaner

All Lens Care Systems

Rewetting	BAUSCH & LOMB® ReNu® Rewetting Drops
	BAUSCH & LOMB® SENSITIVE EYES® Drops

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- **Clean** one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface, and put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning and rinsing, ***disinfect*** lenses using the system recommended by the manufacturer and/or the eye care practitioner.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- After removing the lenses from the lens case, empty and rinse the lens storage case with solution as recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with storage solution. Replace lens case at regular intervals.
- Eye care practitioners may recommend a **lubricating/rewetting** solution which can be used to wet (lubricate)

comfortable.

- Lenses prescribed in a frequent replacement progra should be thrown away after the recommended wea period prescribed by the practitioner.

Heat (Thermal) Lens Disinfection:

- **After cleaning** and thoroughly rinsing contact lense recommended solutions, prepare the empty lens st case. **To keep the lenses wet during disinfection,** solution that is recommended by the lens manufact and/or the eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with fresh s solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens case.
- Put the lens storage case into the disinfection unit follow the disinfection unit manufacturer's directio operating the unit (turning the unit on, assuring th works, and leaving it on for a sufficient time to dis the lenses).
- Before reinsertion of the lenses, no rinsing is nece unless the eye care practitioner recommends rinsi

Emergency (Alternate) Method for Heat (Thermal) Disinfection:

- If a heat disinfection unit is not available, place th closed storage container which contains the lense pan of already boiling water. Leave the closed len

individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear to determine the corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens, as determined by the prescribing eye care practitiner. (See the factors discussed in the Warnings section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care practitioner.

LENS CARE DIRECTIONS

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient:

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

Always wash, rinse, and dry hands before handling contact lenses.

Always use **fresh unexpired** lens care solutions.

Use the recommended system of lens care, either heat (thermal) or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. **Do not alternate or mix lens care systems unless indicated on solution labeling.**

Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.

- Lenses should be **cleaned, rinsed, and disinfected** each time they are removed. **Cleaning and rinsing** are necessary to remove mucus and film from the lens surface. **Disinfecting** is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution **does not substitute for disinfection.**

LENS CARE PRODUCT CHART

The following solutions are recommended by Bausch & Lomb for use with BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses; however, eye care practitioners may recommend alternative products and procedures for their patients. All components necessary for lens disinfection, cleaning and storage are available in BAUSCH & LOMB® Care Kits.

Thermal Lens Care System

Action	Care Product
Cleaning	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Rinsing, Disinfecting & Storing	Commercially available Heat Disinfection Unit for Contact Lenses used with:
	BAUSCH & LOMB® ReNu® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray
	BAUSCH & LOMB® SENSITIVE EYES® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Plus
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Thermal Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® SENSITIVE EYES® Enzymatic Contact Lens Cleaner

Chemical Lens Care System

Action	Care Product
Cleaning	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Disinfecting & Storing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
Rinsing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Saline Solution
	BAUSCH & LOMB® ReNu® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray
	BAUSCH & LOMB® SENSITIVE EYES® Plus
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner

ISION CORRECTION USE

AUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility inted Contact Lenses.

pherical Lenses for: Nearsightedness (Myopia), arsightedness (Hyperopia), Not-Aphakic.

ESCRIPTION

he BAUSCH & LOMB® SofLens66™ (alphafilcon A) isibility Tinted Contact Lens is available as a spherical ns. The lens material (alphafilcon A) is a copolymer of -hydroxethyl methacrylate, N-vinyl pyrrolidinone and -tertiary butyl-2-hydroxycyclohexylmethacrylate, and is 3% water by weight when immersed in a sterile solution of odium chloride and a borate buffer. This lens is nted blue with up to 100 ppm of reactive blue dye 246. he BAUSCH & LOMB® SofLens66™ (alphafilcon A) isibility Tinted Contact Lens is a hemispherical shell of e following dimensions:

Diameter:	13.5mm to 15.0mm
Center Thickness:	0.05mm to 0.35mm
Base Curve:	7.5mm t0 9.5mm
Powers (Spherical):	+8.00D to -20.00D

ie physical/optical properties of the lens are:

ecific Gravity:	1.075
efractive Index:	1.390
ght Transmittance Tinted:	C.I.E. value—approximately 99%
ater Content:	66%
ygen Permeability:*	32

)K=32 x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg) 35° C (Polarographic Method)

ACTIONS

In its hydrated state, the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

INDICATIONS

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

NOTE: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications

The lens may be disinfected using either a heat or chemical disinfection system. Eye Care Practitioners may prescribe the lens for frequent/planned replacement wearing schedule,with cleaning, disinfection and scheduled replacement of the lens. The lens may be prescribed in powers ranging from +8.00D to -20.00D.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

After a thorough eye examination, including appropriate medical background, patients must be fully apprised by the prescribing practitioner of all the risks with contact lens wear. Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision.**
- The need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be emphasized to the patient
- Studies have shown that contact lens wearers who are

smokers have a higher incidence of adverse reactions than nonsmokers

XTENDED WEAR

The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper ens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage o the lens; improper fitting; length of wearing time; and he presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is eported to be associated with a higher incidence and legree of epithelial microcysts and infiltrates, and epithelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

The reversibility of endothelial effects of contact lens wear as not been conclusively established. As a result, practioners views of extended wearing time vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods from 1 to 7 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen.

Some practitioners also recommend frequent replacement of lenses at intervals such as one to two weeks. Other practitioners may prescribe disposable contact lens wear where lenses are disposed of at each removal.

- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promptly contact his or her eye care practitioner.

PRECAUTIONS

Special Precautions for Eye Care Practitioners:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on eye should be carefully monitored by the prescribing eye care practitioner.

- Fluorescein should not be used while the patient is wearing the lenses, because the lenses will become discolored. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before reinserting the lenses. If replaced too soon, the lenses may absorb residual fluorescein.

- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
  - Never use solutions recommended for conventional hard contact lenses only.
  - Chemical disinfection solutions should not be used with heat **unless** specifically indicated on product labeling for use in both heat and chemical disinfection.
  - Always use **fresh unexpired** lens care solutions.
  - Always follow directions in the package inserts for the use of contact lens solutions.
  - Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
  - Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
  - Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried Out (Dehydrated) Lens if lens surface does become dried out.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to **immediately** consult his or her eye care practitioner.
- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning/disinfecting, storing and wearing instructions in the Patient Information Booklet for the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during water activities and other sports.
- Inform the doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always discard lenses and lenses worn on a frequent/planned replacement wearing schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing, and eye care practitioners should conduct early and frequent follow-up examination to determine ocular response to extended wear.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

ADVERSE REACTIONS

The patient should be informed that the following problems may occur:

- Eye stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she shou instructed to:

- **Immediately remove lenses.**
- If the discomfort or problem stops, then look closel lens. If the lens is in any way damaged, **do not put t** back on the eye. Place the lens in the storage case a contact the eye care practitioner. If the lens has dirt, eyelash, or other foreign body on it, or the problem and the lens appears undamaged, the patient should oughly clean, rinse, and disinfect the lenses; then re them. After reinsertion, if the problem continues, the patient should **immediately remove the lenses and consult the eye care practitioner.**

If the above symptoms continue after removal of the l or upon reinsertion of a lens, or upon insertion of a ne lens, the patient should **immediately remove the lens contact their eye care practitioner** or physician, who determine the need for examination, treatment or refe without delay. (See Important Treatment Information f Adverse Reactions.) A serious condition such as infec corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactio such as abrasions, epithelial stinging or bacterial conj tivitis must be managed and treated carefully to avoid serious complications.

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Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be amibiguous in its early stage. Signs and symptoms of infectious corneal ulceration include discomfort, pain, inflammation, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steroids or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

FITTING

Conventional methods of fitting contact lenses apply to BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses. It is very important for the eye care practitioner to give the patient the Patient Information booklet for SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens and review it with the patient. For a detailed description of the fitting techniques, refer to the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens Professional Fitting and Information Guide, copies of which are available from:

Bausch & Lomb Incorporated
Rochester, New York 14692

Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720

WEARING SCHEDULE

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

Daily Wear:

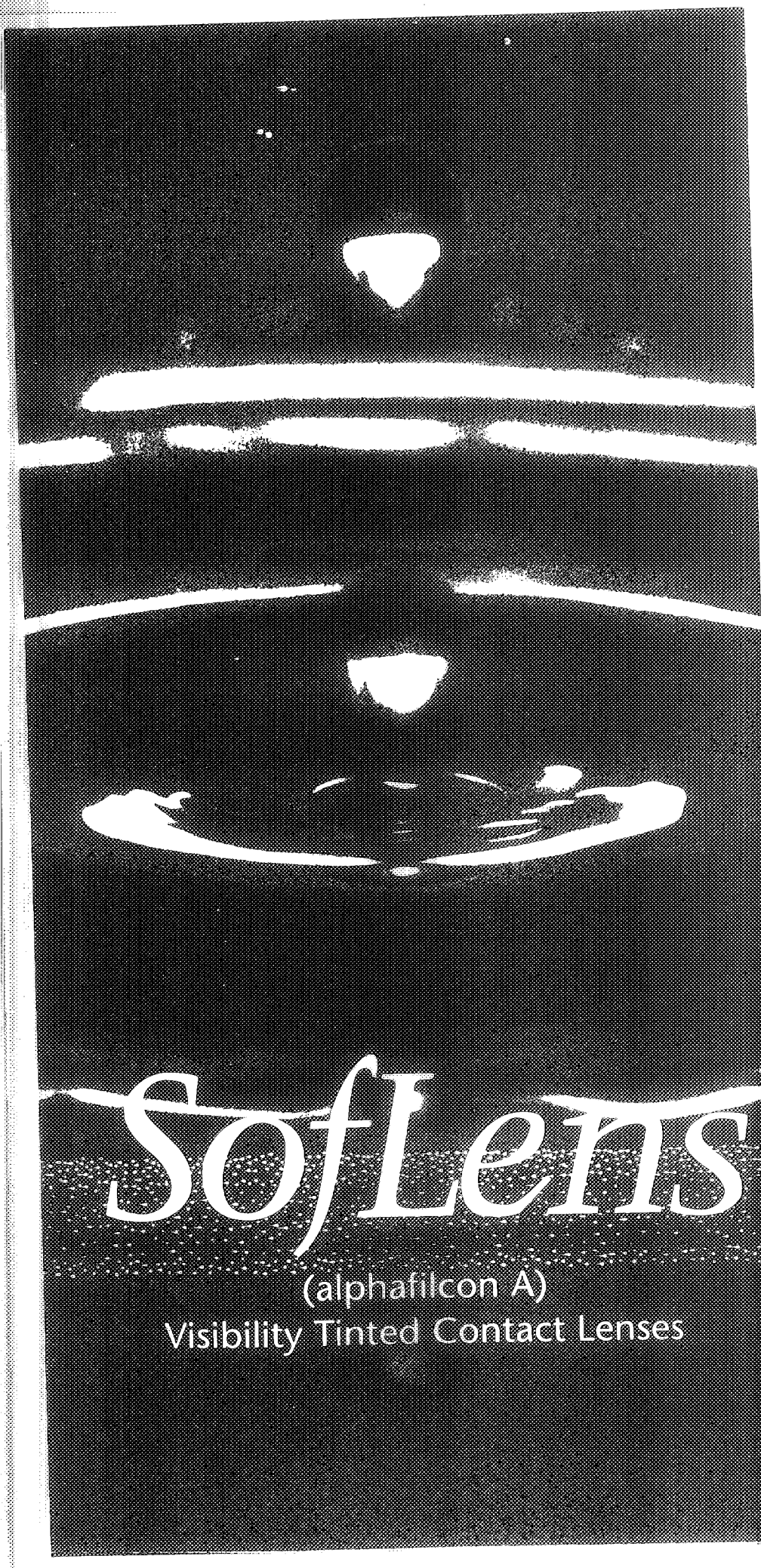
There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients.

The wearing schedule should be dertermined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patient.

Extended Wear (Greater than 24 hours or while asleep):

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgement. Bausch & Lomb recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of daily wear, and then gradual introduction of extended wear one night at a time, unless

FITTING GUIDE



SoLens 66

(alphafilcon A)
Visibility Tinted Contact Lenses

BAUSCH
& LOMB

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***CAUTION:** Federal (U.S.A.) Law Prohibits Dispensing Without Prescription.*

***IMPORTANT:** This Fitting Guide has been developed to provide practitioners with information covering characteristics of the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens and to illustrate fitting procedures. It is effective as of 12/96 and supersedes all prior fitting guides for the product described. Please read carefully and keep this information for future use.*

Introduction

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens is made from a copolymer with a water content of 66% by weight.

For a complete listing of available lens parameters, please refer to LENS PARAMETERS AVAILABLE.

Product Description

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens is available as a spherical lens. The lens material (alphafilcon A) is a copolymer of 2-hydroxyethyl methacrylate, N-vinyl pyrrolidinone and 4-tertiary butyl-2-hydroxycyclohexylmethacrylate, and is 66% water by weight when immersed in a sterile solution of sodium chloride and a borate buffer. This lens is tinted blue with up to 100 ppm of reactive blue dye 246.

The physical/optical properties of the lens are:

Specific Gravity: 1.075
Refractive Index: 1.390

Light Transmittance Tinted:
C.I.E. value—approximately 99%
Water Content: 66%
*Oxygen Permeability:** 32
*$DK = 32 \times 10^{-11}$ $[cm^3O_2\ (STP) \times cm)/(sec \times cm^2 \times mmHg)$ @35° C (Polarographic Method)

Lens Parameters Available

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:
Diameter: 14.2mm
Center Thickness: 0.09mm to 0.12mm

Base Curve: The base curve is a spherical surface flatter than the corneal curvature. The base curve is available in 8.4mm (F/M) and 8.1mm (S/M). (Refer to "Selection of Patients" section for explanation.)

Powers: (Spherical):
-0.50D to -6.00D in 0.25D steps
-6.00D to -9.00D in 0.50D steps

How The Lens Works (Actions)

In its hydrated state, the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens when placed on the cornea acts as a refracting medium to focus light rays on the retina.

Indications

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of the lens, as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

Note: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

The lens may be disinfected using either a heat or chemical disinfection system. Eye Care Practitioners may prescribe the lens for frequent/planned replacement wearing schedule, with cleaning, disinfection and scheduled replacement of the lens. The lens may be prescribed in powers ranging from +8.00D to -20.00D.

Contraindications (Reasons Not To Use)

DO NOT USE the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated.

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Warnings

After a thorough eye examination, including appropriate medical background, patients must be fully apprised by the prescribing practitioner of all the risks with contact lens wear. Patients should be advised of the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to the eye. It is essential that patients follow their eye care practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- The need for strict compliance with the care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be emphasized to the patient.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reations than nonsmokers.

EXTENDED WEAR

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens deposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcycsts and infiltrates, and epithelieal polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.

  The reversibility of endothelial effects of contact lens wear has not been conclusively established. As a result, practitioners views of extended wearing times vary from not prescribing extended wear at all to prescribing flexible wearing times from occasional overnight wear to prescribing extended wearing periods from 1 to 7 days with specified intervals of no lens wear for certain patients, with follow-up visits, and with proper care regimen. Some practitioners also recommend frequent replacement of lenses at intervals such as one to two weeks. Other practitioners may prescribe disposable contact lens wear where lenses are disposed of at each removal.
- If a patient experiences eye discomfort, excessive tearing, vision changes, or redness of the eye, the patient should be instructed to **immediately remove lenses** and promply contact his or her eye care practitioner

Precautions

Special Precautions for Eye Care Practitioners:

- Due to the small number of patients enrolled in clinical investigation of lenses, all refractive powers, design configurations, or lens parameters available in the lens material are not evaluated in significant numbers. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

  The potential impact of these factors on the patient's ocular health should be carefully weighed against the patient's need for refractive correction; therefore, the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.
- Fluorescein should not be used while the patient is wearing the lenses, because the lenses will become discolored. Whenever fluorescein is used, flush the eyes with sterile saline solution. Wait at least 5 minutes before reinserting the lenses. If it is not possible to flush the eyes, wait a minimum of 1 hour before reinserting the lenses. If replaced too soon, the lenses may absorb residual fluorescein.
- Before leaving the eye care practitioner's office, the patient should be able to promptly remove lenses or should have someone else available who can remove the lenses for him or her.

Eye care practitioners should carefully instruct patients about the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
  - —Never use solutions recommended for conventional hard contact lenses only.
  - —Chemical disinfection solutions should not be used with heat ***unless*** specifically indicated on product labeling for use in both heat and chemical disinfection.
  - —**Always** use ***fresh unexpired*** lens care solutions.
  - —**Always** follow directions in the package inserts for the use of contact lens solutions.
  - —**Sterile** unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
  - —Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
  - —**Always** keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dried-Out (Dehydrated) Lens if lens surface does become dried out.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, the patient should be instructed to ***immediately*** consult his or her eye care practitioner.
- **Always** wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with the fingers or hands if the hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning/disinfecting, storing and wearing instructions in the Patient Information Booklet for the BAUSCH & LOMB SoftLens66™ (alphafilcon A) Visibility Tinted Contact Lens and those prescribed by the eye care practitioner.
- Never wear lenses beyond the period recommended by the eye care practitioner.
- If aerosol products such as hair spray are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.
- Always handle lenses gently and avoid dropping them.
- Avoid all harmful or irritating vapors and fumes while wearing lenses.
- Ask the eye care practitioner about wearing lenses during water activities and other sports.
- Inform the doctor (health care practitioner) about being a contact lens wearer.

  Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into the hand.
- Do not touch the lens with fingernails.
- Always discard lenses worn on a frequent/planned replacement wearing schedule after the recommended wearing schedule prescribed by the eye care practitioner.
- Always contact the eye care practitioner before using any medicine in the eyes.
- Always inform the employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that the patient not wear contact lenses.
- Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis. Patients should be carefully evaluated for extended wear prior to prescription and dispensing, and eye care practitioners should conduct early and frequent follow-up examination to determine ocular response to extended wear.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of the patient's eyes. The patient should be instructed as to a recommended follow-up schedule.

Adverse Reactions

The patient should be informed that the following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If the patient notices any of the above, he or she should be instructed to:

- ***Immediately remove lenses.***
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, ***do not*** put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the

problem stops and the lens appears undamaged, the patient should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, the patient should ***immediately remove the lenses and consult the eye care practitioner.***

If the above symptoms continue after removal of the lens, or upon reinsertion of a lens, or upon insertion of a new lens, the patient should **immediately remove the lens and contact their eye care practitioner** or physician, who must determine the need for examination, treatment or referral without delay. (See Important Treatment Information for Adverse Reactions.) A serious condition such as infection, corneal ulcer, corneal vascularization, or iritis may be present, and may progress rapidly. Less serious reactions such as abrasions, epithelial stinging or bacterial conjunctivitis must be managed and treated carefully to avoid more serious complications.

Important Treatment Information for Adverse Reactions

Sight-threatening ocular complications associated with contact lens wear can develop rapidly, and therefore early recognition and treatment of problems are critical. Infectious corneal ulceration is one of the most serious potential complications, and may be ambiguous in its early stage. Signs and symptoms of infectious corneal ulceration, purulent discharge, sensitivity to light, cells and flare and corneal infiltrates.

Initial symptoms of a minor abrasion and an early infected ulcer are sometimes similar. Accordingly, such epithelial defect, if not treated properly, may develop into an infected ulcer. In order to prevent serious progression of these conditions, a patient presenting symptoms of abrasions or early ulcers should be evaluated as a potential medical emergency, treated accordingly, and be referred to a corneal specialist when appropriate. Standard therapy for corneal abrasions such as eye patching or the use of steriods or steroid/antibiotic combinations may exacerbate the condition. If the patient is wearing a contact lens on the affected eye when examined, the lens should be removed immediately and the lens and lens care products retained for analysis and culturing.

Selection Of Patients

Persons who require only vision correction and who would not or could not adhere to a recommended care regimen for BAUSCH & LOMB SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses or are unable to place and remove the lenses should not be provided with them. Failure to follow handling and cleaning instructions could lead to serious eye infections which might result in corneal ulcers.

Patient communication is vital because it relates not only to patient selection but also to ensure compliance. It is also necessary to discuss the information contained in the Patient Information Booklet with the patient at the time of the initial examination.

Patients selected to wear BAUSCH & LOMB SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses should be chosen for their motivation to wear contact lenses, general health and cooperation. The eye care practitioner must take care in selecting, examining and instructing contact lens patients. Patient hygiene and willingness to follow practitioner instructions are essential to their success.

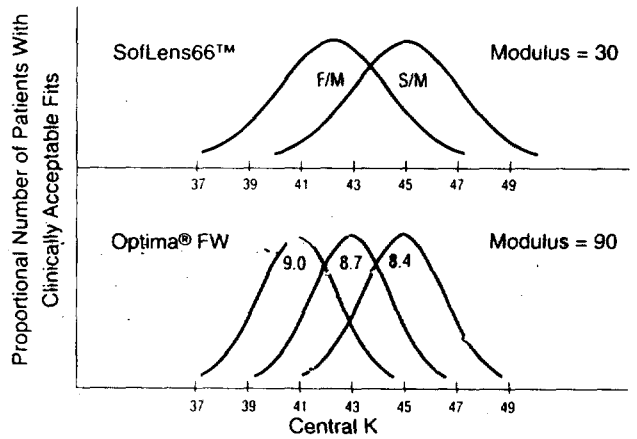
A detailed history is crucial to determining patient needs and expectations. Your patient should be questioned regarding vocation, desired lens wearing time (full or part time), and desired lens usage (reading, recreation or hobbies).

Initial evaluation of the trial lens should be preceded by a complete eye examination, including visual acuity with and without correction at both distance and near, keratometry and slit lamp examination.

It is normal for the patient to experience mild symptoms such as lens awareness, variable vision, occasional tearing (watery eyes) and slight redness during the adaptation period. Although the adaptation period varies for each individual, generally within one week these symptoms will disappear. If these symptoms persist, the patient should be instructed to contact their eye care practitioner.

Base Curve Explanation and Application

The material properties of SofLens66™ coupled with a unique posterior design provides good visual acuity by aligning the central curve closely to the cornea, while providing the sagittal depth necessary for good lens centration. Hence, while the equivalent base curve of the lens, as calculated from the measured lens sag and diameter, is either 8.1mm or 8.4mm in radius, practitioners will find that clinically the SofLens66™ lens fits the average patient's eye more "loosely" than they would anticipate. In fact, practitioners may note that the 8.4mm base curve lens appears to move and center similar to a Bausch & Lomb Polymacon lens with an equivalent base curve of 8.7, or even 9.0mm, while the 8.1mm SofLens66™ appears to move and center similar to a Bausch & Lomb Polymacon lens with an equivalent base curve of 8.4, or 8.7mm. Therefore, the SofLens66™ 8.4 base curve is designated as **F/M**, indicating that the lens fitting characteristics are similar to a Polymacon **M**edium (8.7mm BC) or **F**lat (9.0mm BC) design, and the SofLens66™ 8.1 base curve is designated as **S/M**, indicating that the lens fitting characteristics are similar to a Polymacon **S**teep (8.4mm BC) or **M**edium (8.7mm BC) design. The diagram below indicates the corneal curvature range that can be adequately fit with the SofLens66™ **S/M** and **F/M** base curves, and compares that range to those recommended for Optima® FW contact lenses with 8.4, 8.7, and 9.0 base curves.



Fitting Procedure

1. Pre-fitting Examination

A pre-fitting patient history and examination are necessary to:

- determine whether a patient is a suitable candidate for daily wear contact lenses (consider patient hygiene and mental and physical state).
- make ocular measurements for initial contact lens parameter selection,
- collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include spherocylinder refraction and VA, keratometry, biomicroscopic examination.

2. Initial Lens Power & Base Curve Selection

A. Lens power is determined from the patient's spherical equivalent prescription corrected to the corneal plane. For patients with the flattest corneal curvature flatter than 45.00D, select the F/M base curve as the initial lens. For patients with the flattest corneal curvature steeper than or equal to 45.00D, select the S/M base curve as the initial lens.

B. Allow the lens to remain on the eye long enough (10 to 20 minutes) to achieve a state of equilibrium. Small variations in the tonicity, pH of the lens solutions, and individual tear composition may cause slight changes in fitting characteristics.

C. Allow any increase in tear flow to subside before evaluating the lens. The time required will vary with the individual.

3. Initial Lens Evaluation

A. To determine proper lens parameters observe the lens relationship to the eye using a slit lamp.

- Movement: The lens should provide discernible movement with:
  - —Primary gaze blink
  - —Upgaze blink
  - —Upgaze lag
- Centration: The lens should provide full corneal coverage.

B. Lens evaluation allows the contact lens fitter to evaluate the lens/cornea relationship in the same manner as would be done with any soft lens. If after the lens has settled on the eye, the patient reports lens sensation, or if the lens is moving or decentering excessively, a steeper base curve should be selected. Alternatively, if the patient reports variable vision, or if the lens shows insufficient movement, then a flatter base curve should be selected.

4. Follow-up Care

A. Follow-up examinations are necessary to ensure continued successful contact lens wear. From the day of dispensing, the following schedule is a suggested guideline for follow-up.

- 3 or 4 days post-dispensing
- 10 days
- 1 month
- 3 months
- every six months thereafter

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At the initial follow-up evaluations the eye care practitioner should again reassure the patient that any of the previously described adaptive symptoms are normal, and that the adaptation period should be relatively brief.

B. Prior to a follow-up examination, the contact lenses should be worn for at least 4 continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

C. With lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. Examine the lenses closely for surface deposition and/or damage.

D. After the lens removal, instill sodium fluorescein (unless contraindicated) into the eyes and conduct a thorough biomicroscopy examination.
1. The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization may be indicative of excessive corneal edema.
2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting lens.
3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

Practitioner Fitting Sets

All lenses that have been opened must be discarded after each use.

Wearing Schedule

It is recommended that contact lens wearers see their eye care practitioner twice each year or if directed, more frequently.

Daily Wear:

There may be a tendency for the daily wear patient to over wear the lenses initially. Therefore, the importance of adhering to a proper, initial daily wearing schedule should be stressed to these patients.

The wearing schedule should be determined by the eye care practitioner. The wearing schedule chosen by the eye care practitioner should be provided to the patients.

Extended Wear (Greater than 24 hours or while asleep):

The wearing schedule should be determined by the prescribing eye care practitioner for each individual patient, based upon a full examination and patient history as well as the practitioner's experience and professional judgement. Bausch & Lomb recommends beginning extended wear patients with the recommended initial daily wear schedule, followed by a period of extended wear one night at a time, unless individual considerations indicate otherwise. The practitioner should examine the patient in the early stages of extended wear to determine the corneal response. The lens must be removed, cleaned and disinfected or diposed of and replaced with a new lens, as determined by the prescribing eye care practitioner. (See the factors discussed in the Warnings section.) Once removed, a lens should remain out of the eye for a period of rest overnight or longer, as determined by the prescribing eye care practitioner.

Clinical Assessment

1. Criteria of a Well-fitted Lens

If the initial lens selection fully covers the cornea, provides discernible movement after a blink, is comfortable for the patient and provides satisfactory visual performance, it is a well-fitted lens and can be dispensed.

2. Characteristics of a Tight (Steep) Lens

A lens which is much too steep may subjectively and objectively cause distortion which will vary after a blink. However, if a lens is only marginally steep, the initial subjective and objective vision and comfort findings may be quite good. A marginally steep lens may be differentiated from a properly fitted lens by having the patient gaze upward. A properly fitted lens will tend to slide downward approximately 0.5mm while a steep lens will remain relatively stable in relationship to the cornea, particularly with the blink.

3. Characteristics of a Loose (Flat) Lens

If the lens is too flat, it will:
—decenter, especially on post-blink.
—have a tendency to edge lift inferiorly and sit on the lower lid, rather than positioning between the sclera and palpebral conjunctiva.
—have a tendency to be uncomfortable and irritating with fluctuating vision.
—have a tendency to drop or lag greater than 2.0mm on upgaze post-blink.

Monovision Fitting Guidelines

1. Patient Selection

A. *Monovision Needs Assessment*

For a good prognosis the patient should have adequately corrected distance and near visual acuity in each eye. The amblyopic patient or the patient with significant astigmatism (greater than one [1] diopter) in one eye may not be a good candidate for monovision with the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens.

Occupational and environmental visual demands should be considered. If the patient requires critical vision (visual acuity and stereopsis) it should be determined by trial whether this patient can function adequately with monovision. Monovision contact lens wear may not be optimal for such activities as:
1. visually demanding situations such as operating potentially dangerous machinery or performing other potentially hazardous activities; and
2. driving automobiles (e.g., driving at night). Patients who cannot pass their state drivers license requirements with monovision correction should be advised to not drive with this correction, OR may require that additional over-correction be prescribed.

B. *Patient Education*

All patients do not function equally well with monovision correction. Patients may not perform as well for certain tasks with this correction as they have with bifocal reading glasses. Each patient should understand that monovision, as well as other presbyopic contact lenses, or other alternative, can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks. During the fitting process it is necessary for the patient to realize the disadvantages as well as the advantages of clear near vision in straight ahead and upward gaze that monovision contact lenses provide.

2. Eye Selection

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used.

A. *Ocular Preference Determination Methods*

Method 1—Determine which eye is the "sighting dominant eye." Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2—Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes. Determine whether the patient functions best with the near add lens over the right or left eye.

B. *Refractive Error Method*

For anisometropic corrections, it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

C. *Visual Demands Method*

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction correct the eye on that side for near.

Example: A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. Special Fitting Considerations

Unilateral Lens Correction

There are circumstances where only one contact lens is required. As an example, an emmetropic patient would only require a near lens while a bilateral myope may require only a distance lens.

Example: A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring a +1.50 diopter add who is −2.50 diopters myopic in the right eye and −1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. Near Add Determination

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the

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patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. Trial Lens Fitting

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting guidelines.

Case history and standard clinical evaluation procedure should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distant objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g. typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions is completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. Adaptation

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.

7. Other Suggestions

The success of the monovision technique may be further improved by having your patient follow the suggestions below.

—Having a third contact lens (distance power) to use when critical distance viewing is needed.

—Having a third contact lens (near power) to use when critical near viewing is needed.

—Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. This is particularly applicable for those patients who cannot meet state licensing requirements with a monovision correction.

—Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

—Reverse the distance and near eyes if a patient is having trouble adapting.

—Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.

—Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

** The decision to fit a patient with a monovision correction is most appropriately left to the eye care practitioner in conjunction with the patient after carefully considering the patient's needs.*

** All patients should be supplied with a copy of the SofLens66 ™ (alphafilcon A) Visibility Tinted Contact Lens Patient Information Booklet.*

Handling Of Lenses

Patient Lens Care Directions:

Eye care practitioners should review with the patient lens care directions, including both basic lens care information and specific instructions on the lens care regimen recommended for the patient.

General Lens Care (To First Clean and Rinse, Then Disinfect Lenses)

Basic Instructions:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use ***fresh unexpired*** lens care solutions.
- Use the recommended system of lens care, either heat (thermal) or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. ***Do not alternate or mix lens care systems unless indicated on solution labeling.***
- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting lenses. Do not put lenses in the mouth.

Thermal Lens Care System

- Lenses should be ***cleaned, rinsed, and disinfected*** each time they are removed. ***Cleaning and rinsing*** are necessary to remove mucus and film from the lens surface. ***Disinfecting*** is necessary to destroy harmful germs.
- Always remove, clean, rinse, enzyme and disinfect lenses according to the schedule prescribed by the eye care practitioner. The use of an enzyme or any cleaning solution ***does not substitute for disinfection.***

Lens Deposits and Use of Enzymatic Cleaning Procedure:

Enzyme cleaning may be recommended by the eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of the patient's lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, the patient should carefully follow the instructions in the enzymatic cleaning labeling.

Heat (Thermal) Lens Disinfection:

- ***After cleaning*** and thoroughly rinsing contact lenses with recommended solutions, prepare the empty lens storage case. ***To keep the lenses wet during disinfection,*** use the solution that is recommended by the lens manufacturer and/or the eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.
- Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Action	*Care Product*
Cleaning	BAUSCH & LOMB SENSITIVE EYES Daily Cleaner
Rinsing, Disinfecting & Storing	Commercially available Heat Disinfection Unit for Contact Lenses used with: BAUSCH & LOMB® ReNu® Saline Solution BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray BAUSCH & LOMB® SENSITIVE EYES® Saline Solution BAUSCH & LOMB® SENSITIVE EYES® Plus
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Thermal Enzymatic Contact Lens Cleaner BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner BAUSCH & LOMB® SENSITIVE EYES® Enzymatic Contact Lens Cleaner

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Emergency (Alternate) Method for Heat (Thermal) Disinfection:

- If a heat disinfection unit is not available, place the tightly closed storage container which contains the lenses into a pan of already boiling water. Leave the closed lens case in the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes.) Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lens.

Note: *Use of heat disinfection unit should be resumed as soon as possible.*

- Leave the lenses in the unopened storage case until ready to put on the eyes.
- Before reinsertion of the lenses, no rinsing is necessary unless the eye care practitioner recommends rinsing.

Chemical (Not Heat) Disinfection:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- ***After cleaning and rinising,*** to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or the eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses ***must be neutralized*** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- ***Do not heat the disinfection solution and lenses.***
- Leave the lenses in the unopened storage case until ready to put on the eyes.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to the eyes. A thorough rinse in fresh sterile saline solution prior to placement on the eye should reduce the potential for irritation.

Chemical Lens Care System

Action	*Care Product*
Cleaning	BAUSCH & LOMB ReNu® Multi-Purpose Solution
	BAUSCH & LOMB SENSITIVE EYES Daily Cleaner
Disinfecting & Storing	BAUSCH & LOMB ReNu® Multi-Purpose Solution
Rinsing	BAUSCH & LOMB ReNu® Multi-Purpose Solution
	BAUSCH & LOMB SENSITIVE EYES Saline Solution
	BAUSCH & LOMB ReNu® Saline Solution
	BAUSCH & LOMB SENSITIVE EYES Sterile Saline Spray
	BAUSCH & LOMB SENSITIVE EYES Plus
Enzymatic Protein Removal	BAUSCH & LOMB ReNu® Effervescent Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB SENSITIVE EYES Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB ReNu® 1 Step Enzymatic Contact Lens Cleaner

All Lens Care Systems

Action	*Care Product*
Rewetting	BAUSCH & LOMB ReNu Rewetting Drops
	BAUSCH & LOMB SENSITIVE EYES Drops

Note: Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.

Care for a Dried-Out (Dehydrated) or Dry Lens:

If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, such as a counter top, apply saline or rinsing solution before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least one hour until it returns to a soft state.
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, the lens should not be used until examined by the eye care practitioner.

Care for a Sticking (Nonmoving) Lens:

If the lens sticks (stops moving), the patient should be instructed to use a lubricating or rewetting solution in their eye. The patient should be instructed to not use plain water, or anything other than the recommended solutions. The patient should be instructed to contact the eye care practitioner if the lens does not begin to move upon blinking after several applications of the solution.

Reporting Of Adverse Reactions

All serious adverse experiences and adverse reactions observed in patients wearing BAUSCH & LOMB SoftLens66™ (alphafilcon A) Visibility Tinted Contact Lens or experienced with the lenses should be reported to:

Bausch & Lomb Incorporated
Rochester, New York 14692

Toll Free Telephone Number
In the Continental U.S., Alaska, Hawaii
1-800-828-9030
In New York State
1-800-462-1720

How Supplied

Each sterile lens is supplied in a plastic package containing borate buffered saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere, diameter and expiration date.

BAUSCH & LOMB INCORPORATED
Rochester, NY 14692

BAUSCH & LOMB

SofLens66™

(alphafilcon A)
Visibility Tinted Contact Lenses

PATIENT INFORMATION BOOKLET

DPB0004 12/96 SL-2074-2

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CAUTION: *Federal (U.S.A.) Law Prohibits Dispensing Without a Prescription*

Introduction

The instructions in this booklet apply to the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses. If you have received or are considering another brand of contact lenses, do not use this booklet. Ask your eye care practitioner for the patient booklet or instructions that apply to your brand or type of contact lenses. For BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lenses, it is essential to your safety that you read and understand the information and instructions in this booklet, and have your eye care practitioner answer any questions, both before and after you receive contact lenses.

Wearing contact lenses is different from wearing eyeglasses. Because they are worn directly on your eyes, contact lenses affect the way in which your eyes function. These effects tend to increase with the length of time that the lenses remain on your eyes between removals. Although the great majority of people successfully wear contact lenses without problems, before you decide whether to begin or to continue wearing contact lenses for daily wear or extended wear, you must discuss with your eye care practitioner the effects of contact lenses on your eyes and the risks associated with wearing contact lenses, which are greater with extended wear. You also must read the sections of this booklet entitled "Warnings", "Adverse Reactions", "Precautions", and "Wearing Restrictions and Indications". Ask your eye care practitioner to explain anything that you do not understand, including any additional restrictions given to you by your eye care practitioner.

You also need to remember that soft contact lenses, including those covered by this booklet, are made of a type of plastic that absorbs liquids, vapors, and small particles, and, for some people, may collect deposits from your natural eye fluids. Therefore, you must strictly follow the instructions contained in the sections of this booklet entitled "Caring For Your Lenses", as well as the written information leaflets accompanying the lens care products that you buy and any other instructions given to you by your eye care practitioner. Any failure to follow these instructions and the wearing restrictions will increase the chances of contamination, damage to the lenses, or a build-up of deposits on the lenses, which can lead to serious, sight-threatening eye infections and injuries.

Adherence to your prescribed wearing schedule and replacement schedule if on a Frequent Replacement Program, and regular check-up visits to your eye care practitioner are also necessary for the proper and safe use of contact lenses. Spaces are provided in the back of this booklet for you to record your personal wearing schedule and schedule of follow-up visits. Soft contact lenses generally are comfortable from the beginning. Therefore, be sure to follow the wearing schedule prescribed for you, and do not overwear your lenses simply because they remain comfortable and you are not experiencing a problem. Only your eye care practitioner, through a professional examination, can determine how your eyes are reacting to the contact lenses and whether there are any early signs of possible problems.

Finally, if problems or symptoms should occur, immediately remove your lenses and follow the steps described in the sections of this booklet entitled "Warnings" and "Adverse Reactions". Prompt attention to problems is essential and may require immediate professional care.

Remember, when wearing soft contact lenses your eyes should look and feel good, and your vision should be clear.

Wearing Restrictions and Indications

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals for cleaning and disinfection or disposal of the lens as recommended by the eye care practitioner. The lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity.

Note: See the WARNINGS reference to the relationship between lens wearing schedule and corneal complications.

The lens may be disinfected using either a heat or chemical disinfection system. Eye Care Practitioners may prescribe the lens for frequent/planned replacement wearing schedule, with cleaning, disinfection and scheduled replacement of the lens. The lens may be prescribed in powers ranging from +8.00D to -20.00D.

- Keep fresh solution accessible when you wear your lenses, in case you have to remove your lenses immediately upon the appearance of a problem or symptom.
- Do not use aerosol products such as hair spray while wearing your lenses. The lenses may absorb the spray, resulting in injury to the eye and damage to the lens.
- Avoid wearing the lenses around fumes, irritating vapors, smoky or dusty conditions. The lenses may absorb the chemicals or particles, resulting in injury to the eye.
- Avoid rubbing your eyes with the lenses in, which can irritate the eye or dislodge the lens.
- Keep your eyes closed lightly when washing or showering to keep water and soaps out of the eyes, which can cause loss of the lenses, contamination or injury to the eye.
- If you get something in your eye, remove the lens immediately. Do not replace the lens until your eye feels normal, and after you have cleaned and disinfected the lens.
- Tell your regular physician and every other doctor that you visit, that you wear contact lenses and the type of lenses that you wear. If you are admitted to a hospital, also tell your nurses that you wear contact lenses.
- Do not use any eye drops, ointments, or medicines in your eye unless they are specifically approved by your eye care practitioner or physician. Some drops, ointments, or medicines will cause injury to the eye if used by a contact lens wearer.

- Ask your eye care practitioner whether there are any other wearing restrictions that apply to you. Write those restrictions in the spaces provided below and follow them carefully:

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Contraindications (Reasons Not To Use)

DO NOT USE the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or Thimerosal, in a solution which is to be used to care for the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

Warnings

You should be aware of and fully discuss with your eye care practitioner the following warnings pertaining to contact lens wear:

- Problems with contact lenses and lens care products could result in **serious injury** to your eye. It is essential that you follow your eyecare practitioner's direction and all labeling instructions for proper use of lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to **loss of vision**.
- Strict compliance with your care regimen including cleaning of the lens case, wearing restrictions, wearing schedule, and follow-up visit schedule must be followed.
- Studies have shown that contact lens wearers who are smokers have a higher incidence of adverse reactions than nonsmokers.

EXTENDED WEAR

- The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses. The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals, beginning with the first overnight use. Some researchers believe that these complications are caused by one or more of the following: a weakening of the cornea's resistance to infections, particularly during a closed-eye condition, as a result of hypoxia; an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms, particularly when a regular periodic lens removal and disinfecting or disposal schedule has not been adhered to by the patient; improper lens disinfection or cleaning by the patient; contamination of lens care products; poor personal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule; accumulation of lens desposits; damage to the lens; improper fitting; length of wearing time; and the presence of ocular debris or environmental contaminants. While the great majority of patients successfully wear contact lenses, extended wear of lenses also is reported to be associated with a higher incidence and degree of epithelial microcycsts and infiltrates, and epithelial polymegathism, which require consideration of discontinuation or restriction of extended wear. The epithelial conditions are reversible upon discontinuation of extended wear.
- If you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, you should **immediately remove lenses** and promptly contact your eyecare practitioner.

Precautions

You should be aware of and fully discuss with your eye care practitioner the following care regimen and safety precautions:

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions.
  —Never use solutions recommended for conventional hard contact lenses only.
  —Chemical disinfection solutions should not be used with heat ***unless*** specifically indicated on product labeling for use in both heat and chemical disinfection.
  —Always use ***fresh unexpired*** lens care solutions.
  —Always follow directions in the package inserts for the use of contact lens solutions.
  —Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
  —Do not use saliva or anything other than the recommended solutions for lubricating or wetting your lenses.
  —Always keep your lenses completely immersed in the recommended storage solution when your lenses are not being worn. Prolonged periods of drying can damage lenses. Follow the lens care directions for Care for a Dehydrated (Dried-Out) Lens if the lens surface does become dried out.
- If the lens sticks (stops moving) on your eye, follow the recommended directions on Care for a Sticking Lens. The lens should move freely on your eye for the continued health of your eye. If nonmovement of the lens continues, you should ***immediately*** consult your eye care practitioner.
- Always wash and rinse your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in your eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Do not touch contact lenses with your fingers or hands if your hands are not free of foreign materials, as microscopic scratches of the lenses may occur, causing distorted vision and/or injury to your eye.
- Carefully follow the handling, insertion, removal, cleaning/disinfecting, storing and wearing instructions in this Patient Information Booklet for the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens and those prescribed by your eye care practitioner.
- Never wear lenses beyond the period recommended by your eye care practitioner.
- Always handle lenses gently and avoid dropping them.
- Ask your eye care practitioner about wearing lenses during water activities and other sports.

- Inform your doctor (health care practitioner) about being a contact lens wearer.
- Never use tweezers or other tools to remove lenses from the lens container unless specifically indicated for that use. Pour the lens into your hand.
- Do not touch the lens with your fingernails.
- Always discard lenses worn on a frequent/planned replacement schedule after the recommended wearing schedule prescribed by your eye care practitioner.
- Always contact your eye care practitioner before using any medicine in your eyes.
- Always inform your employer of being a contact lens wearer. Some jobs may require use of eye protection equipment or may require that you not wear contact lenses.
- As with any contact lens, follow-up visits are necessary to assure the continuing health of your eyes. You should be instructed as to a recommended follow-up schedule.

Adverse Reactions (Problems And What To Do)

The following problems may occur:

- Eyes stinging, burning, itching (irritation), or other eye pain
- Comfort is less than when lens was first placed on eye
- Abnormal feeling of something in the eye (foreign body, scratched area)
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

If you notice any of the above, you should:

- ***Immediately remove your lenses.***
- If the discomfort or problem stops, then look closely at the lens. If the lens is in any way damaged, ***do not*** put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner. If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, you should thoroughly clean, rinse, and disinfect the lenses; then reinsert them. After reinsertion, if the problem continues, you should ***immediately remove the lenses and consult your eye care practitioner.***

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, or iritis may be present. You should ***keep lens off your eye and seek immediate*** professional identification of the problem and prompt treatment to avoid serious eye damage.

Personal Cleanliness and Lens Handling

1. Preparing the Lens for Wearing:
It is essential that you learn and use good hygienic methods in the care and handling of your new lenses. Cleanliness is the first and most important aspect of proper contact lens care. In particular, your hands should be clean and free of any foreign substances when you handle your lenses. The procedures are:

- Always wash your hands thoroughly with a mild soap, rinse completely, and dry with a lint-free towel before touching your lenses.
- Avoid the use of soaps containing cold cream, lotion, or oily cosmetics before handling your lenses, since these substances may come into contact with the lenses and interfere with successful wearing.
- Handle your lenses with your fingertips, and be careful to avoid contact with fingernails. It is helpful to keep your fingernails short and smooth.
- Start off correctly by getting into the habit of always using proper hygienic procedures so that they become automatic.

2. Handling the Lenses:

- Develop the habit of always working with the same lens first to avoid mixups.
- Remove the lens from its storage case and examine it to be sure that it is moist, clean, clear, and free of any nicks or tears.
- Should you accidentally place an inside-out lens on your eye, one of the following signs should signal you to remove and replace it correctly.
  a. Less than usual comfort
  b. The lens may fold on the eye
  c. Excessive lens movement on blink
  d. Blurred vision
- If the lens folds and sticks together: Place the lens in the palm of your hand and wet thoroughly with an appropriate rinsing or storing solution. Refer to the Lens Care Products Chart for the solutions recommended by Bausch & Lomb. Then GENTLY rub the lens between your index finger and palm in a gentle back and forth motion.
- If this gentle rubbing does not work, soak the lens in one of the above solutions contained in your lens case until the lens has resumed its normal shape. If the lens flattens or drapes across your finger, the lens or your finger may be too wet. To correct this, dry your finger by transferring the lens several times from one index finger to the other, drying the opposite finger each time.
- Keep the lens wet in the recommended solutions.
- Never place a lens on the eye unless it has been fully hydrated (wet) with an appropriate rinsing or storing solution. Refer to the Lens Care Products Chart for the solutions recommended by Bausch & Lomb.

3. Placing the Lens on the Eye:
There are other methods of lens placement. If the above method is difficult for you, your eye care practitioner will provide you with an alternate method.

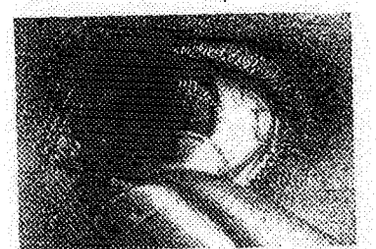
Note: If after placement of the lens, your vision is blurred, check for the following:

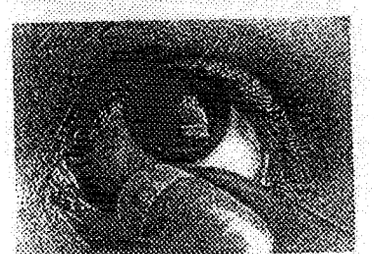
- The lens is not centered on the eye (see "Centering the Lens," next in this booklet).
- If the lens is centered, remove the lens (see "Removing the Lens" section) and check for the following:
  a. Cosmetics or oils on the lens. Clean, rinse, disinfect, and place on the eye again.
  b. The lens is on the wrong eye.
  c. The lens is inside-out (it would also not be as comfortable as normal).

If you find that your vision is still blurred after checking the above possibilities, remove both lenses and consult your eye care practitioner.

The One Hand Placement Technique

Place the lens on your index finger. Head up, looking straight ahead, pull down your lower eyelid with the middle finger of your placement hand. Look up steadily at a point above you. Then place the lens on the lower white part of your eye. Remove your index finger and slowly release the lower lid. Look down to position the lens properly. Close your eyes for a moment, the lens will center itself on your eye.



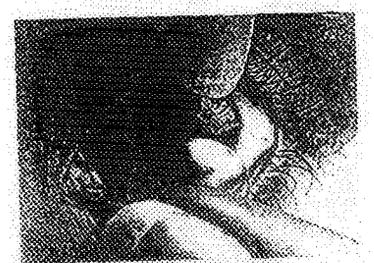


The Two Hand Placement Technique

With the lens on your index finger, use the middle finger of the other hand to pull the upper lid against the brow. Use the middle finger of your placement hand to pull down the lower lid and then place the lens centrally on your eye. While holding this position, look downward to position the lens properly. Slowly release your eyelids.

If the lens feels uncomfortable, then:

Look in a mirror and gently place a finger on the edge of the contact lens and slowly slide the lens away from your nose while looking in the opposite direction. Then, by blinking, the lens will recenter itself. If the lens still feels uncomfortable, follow the steps described in the section of this booklet entitled "Adverse Reactions".



4. Centering the Lens:
Very rarely, a lens that is on the cornea will be displaced onto the white part of the eye during lens wear. This can also occur during placement and removal of the lenses if the correct techniques are not performed properly. To center a lens follow one of the procedures below.

- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, gently place a finger on the contact lens and gently slide the lens towards the center of the eye.
  Or
- Hold the upper and lower eyelids open with your fingers. Then, while looking in a mirror, move your eye towards the lens to place it on the center of the eye.

5. Removing the Lens:
Always remove the same lens first.

a. Wash, rinse, and dry your hands thoroughly.

b. Always be sure that the lens is in the correct position on your eye before you try to remove it (a sample check of your vision, closing one eye at a time, will tell you if the lens is in the correct position). Look up and slowly pull down your lower lid with the middle finger of your removal hand and place your index finger on the lower edge of the lens. Slide the lens down to the lower white part of your eye. Squeeze the lens lightly between the thumb and index finger and remove it. Avoid sticking the edges of the lens together.

c. Remove the other lens by following the same procedure.

d. Follow the required lens care procedures described under the heading, CARING FOR YOUR LENSES (CLEANING, RINSING, DISINFECTING, ENZYMING, STORAGE AND REWETTING/ LUBRICATING).

Note: If this method of removing your lens is difficult for you, your eye care practitioner will provide you with an alternate method.

Caring for Your Lenses
(Cleaning, Rinsing, Disinfecting, Enzyming, Storage and Rewetting/Lubricating)

1. Basic Instructions:
For continued safe and comfortable wearing of your lenses, it is important that you ***first clean and rinse, then disinfect*** [and neutralize (for hydrogen peroxide systems)] your lenses after each removal, using the care regimen recommended by your eye care practitioner. ***Cleaning and rinsing*** are necessary to remove mucus, secretions, films, or deposits which may have accumulated during wearing. The ideal time to clean your lenses is immediately after removing them. ***Disinfecting*** is necessary to destroy harmful germs.

You should adhere to a recommended care regimen. Failure to follow the regimen may result in development of serious ocular complications as discussed in the WARNINGS section above.

If you require only vision correction, but will not or cannot adhere to a recommended care regimen for your lenses, or are unable to place and remove lenses or have someone available to place and remove them, you should not attempt to get and wear contact lenses.

When you first get your lenses, be sure you have to put the lenses on and remove them while you are in your eye care practitioner's office. At that time you will be provided with a recommended cleaning and disinfection regimen and instructions and warnings for lens care, handling, cleaning, and disinfection. Your eye care practitioner should instruct you about appropriate and adequate procedures and products for your use, and provide you with a copy of this Patient Information Booklet for the BAUSCH & LOMB® SoftLens66™ (alphafilcon A) Visibility Tinted Contact Lens.

For safe contact lens wear, you should know and always practice your lens care routine:

- Always wash, rinse, and dry hands before handling contact lenses.
- Always use ***fresh unexpired*** lens care solutions.
- Use the recommended system of lens care, either heat (thermal) or chemical (not heat) and carefully follow instructions on solution labeling. Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. ***Do not alternate or mix lens care systems unless indicated on solution labeling.***
- Always remove, clean, rinse, enzyme and disinfect your lenses according to the schedule prescribed by your eye care practitioner. The use of an enzyme or any cleaning solution does not substitute for disinfection.

- Do not use saliva or anything other than the recommended solutions for lubricating or rewetting your lenses. Do not put lenses in your mouth.
- Lenses prescribed in a frequent replacement program should be thrown away after the recommended wearing period prescribed by your eye care practitioner.
- Never rinse your lenses in water from the tap. There are two reasons for this:
  a. Tap water contains many impurities that can contaminate or damage your lenses and may lead to eye infection or injury.
  b. You might lose the lens down the drain.

Lens Care Products Chart

The following solutions are recommended by Bausch & Lomb for use with all Bausch & Lomb Contact Lenses; however, eye care practitioners may recommend alternative products and procedures which should be followed by the patient. BAUSCH & LOMB™ Care Kits are available for lens disinfection, cleaning, and storage.

Thermal (Heat) Lens Care System

ACTION	CARE PRODUCT
Cleaning	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Rinsing, Disinfecting & Storing	Commercially available Heat Disinfecting Unit for Contact Lenses used with:
	BAUSCH & LOMB® ReNu® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray
	BAUSCH & LOMB® SENSITIVE EYES® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Plus
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Thermal Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® SENSITIVE EYES® Enzymatic Contact Lens Cleaner

Chemical Lens Care System

ACTION	CARE PRODUCT
Cleaning	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Daily Cleaner
Disinfecting & Storing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
Rinsing	BAUSCH & LOMB® ReNu® Multi-Purpose Solution
	BAUSCH & LOMB® SENSITIVE EYES® Saline Solution
	BAUSCH & LOMB® ReNu® Saline Solution
	BAUSCH & LOMB® SENSITIVE EYES® Sterile Saline Spray
	BAUSCH & LOMB® SENSITIVE EYES® Plus
Enzymatic Protein Removal	BAUSCH & LOMB® ReNu® Effervescent Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® SENSITIVE EYES® Enzymatic Contact Lens Cleaner
	BAUSCH & LOMB® ReNu® 1 Step Enzymatic Contact Lens Cleaner

All Lens Care Systems

ACTION	CARE PRODUCT
Rewetting	BAUSCH & LOMB® ReNu® Rewetting Drops
	BAUSCH & LOMB® SENSITIVE EYES® Drops

- **Note:** Some solutions may have more than one function, which will be indicated on the label. Read the label on the solution bottle, and follow instructions.
- ***Clean*** one lens first (always the same lens first to avoid mixups), rinse the lens thoroughly with recommended saline or disinfecting solution to remove the cleaning solution, mucus, and film from the lens surface. Follow the instructions provided in the cleaning solution labeling. Put that lens into the correct chamber of the lens storage case. Then repeat the procedure for the second lens.
- After cleaning and rinsing ***disinfect*** lenses using the system recommended by your eye care practitioner and/or the lens manufacturer. Follow the instructions provided in the disinfection solution labeling.
- To store lenses, disinfect and leave them in the closed/unopened case until ready to wear. If lenses are not to be used immediately after disinfection, you should consult the labeling of the storage solution for information on lens storage.
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer; then allow the lens case to air dry. When the case is used again, refill it with ***fresh*** storage solution. Replace lens case at regular intervals.
- Your eye care practitioner may recommend a lubricating/rewetting solution for your use. ***Lubricating/ Rewetting*** solutions can be used to wet (lubricate) your lenses while you are wearing them to make them more comfortable.

2. Heat (Thermal) Lens Disinfection:

- ***After cleaning*** and thoroughly rinsing contact lenses with recommended solutions, prepare the empty lens storage case. ***To keep the lenses wet during disinfection,*** use the solution that is recommended by the lens manufacturer and/or your eye care practitioner.
- Wet the lens chambers (sections) with fresh saline solution.
- Put each lens into its correct chamber.
- Fill the chamber of the case to the line with fresh saline solution. Completely cover the lenses.
- Tightly close the top on each chamber of the lens storage case.
- Put the lens storage case into the disinfection unit and follow the disinfection unit manufacturer's directions for operating the unit (turning the unit on, assuring that it works, and leaving it on for a sufficient time to disinfect the lenses).
- Before reinsertion of the lenses, no rinsing is necessary unless your eye care practitioner recommends rinsing.

3. Emergency (Alternate) Method for Heat (Thermal) Disinfection:

- If a heat disinfection unit is not available, place the tightly closed storage container which contains the lenses into a pan of already boiling water. Leave the closed lens case in the pan of boiling water for at least 10 minutes. (Above an altitude of 7,000 feet, boil for at least 15 minutes.) Be careful not to allow the water in the pan to boil away. Remove the pan from the heat and allow it to cool for 30 minutes to complete the disinfection of the lens.

  Note: *Use of heat disinfection unit should be resumed as soon as possible.*
- Leave the lenses in the unopened storage case until ready to put on your eyes.
- Before reinsertion of the lenses, no rinsing is necessary unless your eye care practitioner recommends rinsing.

4. Chemical (Not Heat) Disinfection:

- Clean the contact lenses with a recommended cleaning solution and thoroughly rinse them with a recommended rinsing solution.
- ***After cleaning and rinsing,*** to disinfect, carefully follow the instructions accompanying the disinfecting solution in the care regimen recommended by the lens manufacturer or your eye care practitioner.
- When using hydrogen peroxide lens care systems, lenses ***must be neutralized*** before wearing. Follow the recommendations on the hydrogen peroxide system labeling.
- Thoroughly rinse lenses with a fresh solution recommended for rinsing before inserting and wearing, or follow the instructions on the disinfection solution labeling.
- ***Do not heat the disinfection solution and lenses.***
- Leave the lenses in the unopened storage case until ready to put on your eyes.
- **Caution:** Lenses that are chemically disinfected may absorb ingredients from the disinfecting solution which may be irritating to your eyes. A thorough rinse in fresh sterile saline solution prior to placement on your eye should reduce the potential for irritation.

5. Lens Deposits and Use of Enzymatic Cleaning Procedure:

Enzyme cleaning may be recommended by your eye care practitioner. Enzyme cleaning removes protein deposits on the lens. These deposits cannot be removed with regular cleaners. Removing protein deposits is important for the well-being of your lenses and eyes. If these deposits are not removed, they can damage the lenses and cause irritation.

Enzyme cleaning does NOT replace routine cleaning and disinfecting. For enzyme cleaning, you should carefully follow the instructions in the enzymatic cleaning labeling.

6. Lens Case Cleaning and Maintenance:

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the lens case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals.

7. Care for a Sticking (Nonmoving) Lens:

It is important to the health of your eyes that your contact lenses move freely. If a lens sticks (stops moving), put a few drops of the lubricating or rewetting solution recommended by your eye care practitioner

into your eye. In this case, do not use plain water or anything other than the recommended solutions. Do not attempt to remove a lens that is sticking, which could damage your eye. If the lens does not begin to move when you blink after several applications of the solution or drops, contact your eye care practitioner immediately.

8. Care for a Dehydrated Lens:
If a soft, hydrophilic contact lens is exposed to air while off the eye, it may become dry and brittle and need to be rehydrated. If the lens is adhering to a surface, apply sterile saline before handling.

To rehydrate the lens:

- Handle the lens carefully.
- Place the lens in its storage case and soak the lens in a recommended rinsing and storing solution for at least 1 hour until it returns to a soft state.
- Clean lens first, then disinfect the rehydrated lens using a recommended lens care system.
- If after soaking, the lens does not become soft, if the surface remains dry, DO NOT USE THE LENS UNLESS IT HAS BEEN EXAMINED BY YOUR EYE CARE PRACTITIONER.

9. Emergencies:
If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into your eyes, you should: FLUSH EYES IMMEDIATELY WITH TAP WATER AND THEN REMOVE LENSES PROMPTLY. CONTACT YOUR EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

Instructions for the Monovision Wearer

- You should be aware that as with any type of lens correction, there are advantages and compromises to monovision contact lens therapy. The benefit of clear near vision in straight ahead and upward gaze that is available with monovision may be accompanied by a vision compromise that may reduce your visual acuity and depth perception for distance and near tasks. Some patients have experienced difficulty adapting to it. Symptoms, such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance, may last for a brief minute or for several weeks as adaptation takes place. The longer these symptoms persist, the poorer your prognosis for successful adaptation. You should avoid visually demanding situations during the initial adaptation period. It is recommended that you first wear these contact lenses in familiar situations, which are not visually demanding. For example, it might be better to be a passenger rather than a driver of an automobile during the first few days of lens wear. It is recommended that you only drive with monovision correction if you pass your state drivers license requirements with monovision correction.
- Some monovision patients will never be fully comfortable functioning under low levels of illumination, such as driving at night. If this happens, you may want to discuss with your eye care practitioner having additional contact lenses prescribed so that both eyes are corrected for distance when sharp distance binocular vision is required.

  If you require very sharp near vision during prolonged close work, you may want to have additional contact lenses prescribed so that both eyes are corrected for near when sharp near binocular vision is required.
- Some monovision patients require supplemental spectacles to wear over the monovision correction to provide the clearest vision for critical tasks. You should discuss this with your eye care practitioner.
- It is important that you follow your eye care practitioner's suggestions for adaptation to monovision contact lens therapy. You should discuss any concerns that you may have during and after the adaptation period.
- ***The decision to be fit with a monovision correction is most appropriately left to the eye care practitioner in conjunction with you, after carefully considering and discussing your needs.***

Wearing and Appointment Schedules

Prescribed Wearing Schedule

Day	Wearing Time (Hours)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Appointment Schedule

Your appointments are on

Minimum number of hours lenses to be worn at time of appointment day

Month Year Time

Month Year Time

Month Year Time

Month Year Time

Month Year Time

Personal Wearing Schedule Record

Your eye care practitioner will prescribe your own individual lens wearing schedule and lens replacement schedule if in a frequent replacement program. Use the space below to record your schedule and wearing record.

DAY	DATE	HOURS TO BE WORN	HOURS WORN
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			

DAY	DATE	HOURS TO BE WORN	HOURS WORN
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			

Check-Up Visits

Regular check-up examinations by your eye care practitioner are an important part of wearing contact lenses. It is recommended that you see your eye care practitioner twice each year or if directed, more frequently. Keep all appointments for your check-up visits. If you move to a new city, ask your present eye care practitioner to refer you to a contact lens practitioner in your new location. Use the space below to record your appointments.

Visit Schedule

1. _____
   Date Time

2. _____
   Date Time

3. _____
   Date Time

4. _____
   Date Time

5. _____
   Date Time

6. _____ Date _____ Time

7. _____ Date _____ Time

8. _____ Date _____ Time

9. _____ Date _____ Time

10. _____ Date _____ Time

Patient/Eye Care Practitioner Information:
Eye Care Practitioner Information
(Please fill out for ready use)

Name: _____

Address: _____

Phone: _____

Other Information: _____

_____

_____

_____

Important: In the event that you experience any difficulty wearing your lenses or you do not understand the instructions given you, DO NOT WAIT for your next appointment. TELEPHONE YOUR EYE CARE PRACTITIONER IMMEDIATELY.

Name and Address of Manufacturer:
Bausch & Lomb Incorporated
Rochester, New York 14692